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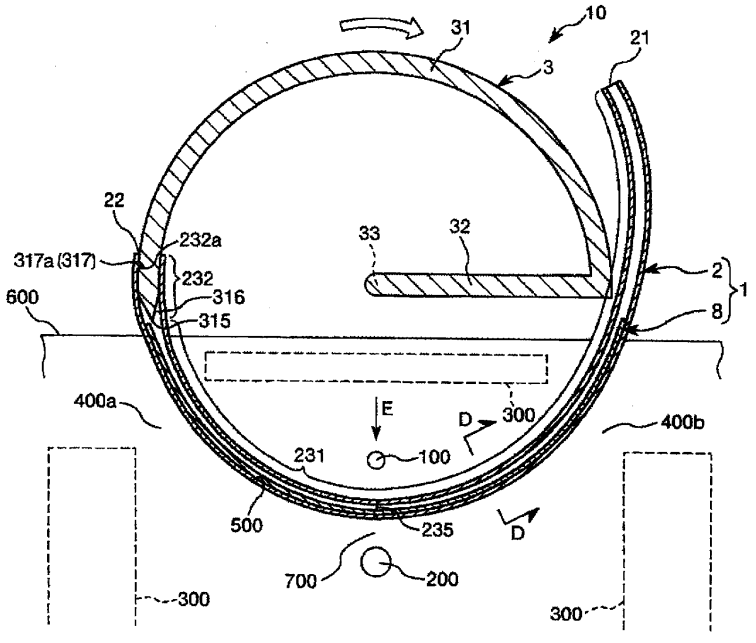
(54) **MEDICAL TUBE, MEDICAL TUBE ASSEMBLY AND PUNCTURE NEEDLE**

(57) A medical tube 2 has an elongated implant 8 inserted therein. The medical tube 2 is a tube having a distal end opening 21 where the distal end thereof is open, and a proximal end opening 22 where the proximal end thereof is open. The medical tube 2 includes a bent region 231 where an intermediate portion in the longitudinal direction of the medical tube 2 is bent and where the bent state is maintained, and a connection portion 232 which is provided near the proximal end opening 22 and to which a puncture needle 31 having a sharp needle tip 315 at the distal end thereof is connected from the needle tip 315 side.

FIG. 4



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Description

Technical Field

[0001] The present invention relates to a medical tube, a medical tube assembly and a puncture needle.

Background Art

[0002] If a person suffers from a urinary incontinence, specifically if a person suffers from a stress urinary incontinence, then urine leakage can be caused by application of abdominal pressure during normal exercise or by laughing, coughing, sneezing or the like. The cause of this may be, for example, that the pelvic floor muscle which is a muscle for supporting the urethra is loosened by birth or the like.

[0003] For the treatment of urinary incontinence, a surgical treatment is effective, in which there is used, for example, a tape-shaped implant called "sling." The sling is indwelled inside the body and the urethra is supported by the sling (see, for example, Patent Document 1). In order to indwell the sling inside the body, an operator would incise the vagina wall with a surgical knife, dissect a living body tissue between the urethra and the vagina, and, by use of a puncture needle or the like, form a piercing hole which communicates with the dissected living body tissue and the outside of the body. Then, the sling is inserted into the piercing hole, and the sling is indwelled in the dissected living body tissue inside the body.

[0004] At the time of inserting the sling into the piercing hole, the inserting operation is conducted with the sling kept inserted in a flexible tube. Since the tube is flexible, however, the tube would be flattened (pressed) by the dissected living body tissue. As a result, there have been cases where the friction between the tube and the living body tissue would make it difficult to carry out the sling-inserting operation.

Prior Art Document

Patent Document

[0005] Patent Document 1: Japanese Patent Laid-Open No. 2010-99499

Summary of Invention

Technical Problem

[0006] It is an object of the present invention to provide a medical tube, a medical tube assembly and a puncture needle that enable an easy and reliable operation at the time of inserting an implant into a living body and indwelling the implant inside the living body.

Technical Solution

[0007] Such an object is achieved by the present invention as described in the following paragraphs (1) to (17).

[0008]

(1) A medical tube configured to have an elongated implant inserted therein includes a tube which has a proximal end opening where the tube is open at a proximal end thereof. The tube includes a bent region where an intermediate portion in a longitudinal direction of the tube is bent and where a bent state is maintained. The tube also includes a connection portion which is provided near the proximal end opening and to which a puncture needle having a sharp needle tip at a distal end thereof is connected from the needle tip side.

(2) The medical tube as described in the aforementioned paragraph (1) is configured such that the tube is rigid at least at the bent region.

(3) The medical tube as described in the aforementioned paragraph (1) or (2) is configured such that the connection portion has a small piece formed by forming at least one slit that penetrates the tube wall of the tube, and bending a portion surrounded by the slit toward an inner side.

(4) The medical tube as described in the aforementioned paragraph (1) or (2) is configured such that the connection portion has a reduced-diameter part where the tube is reduced in inside diameter.

(5) The medical tube as described in any one of the aforementioned paragraphs (1) to (4) is configured such that the bent region is bent in an arc shape.

(6) The medical tube as described in any one of the aforementioned paragraphs (1) to (5) further includes a separation portion which permits the tube to be separated at an intermediate position in the longitudinal direction of the tube.

(7) The medical tube as described in the aforementioned paragraph (6) is configured such that the separation portion is disposed at a central portion in the longitudinal direction of the bent region.

(8) The medical tube as described in the aforementioned paragraph (7) is configured such that the tube is provided with a marker for grasping of the position of the central portion in the longitudinal direction of the bent region.

(9) The medical tube as described in any one of the aforementioned paragraphs (6) to (8) is configured such that the tube is separated by virtue of the separation portion into a first tube on the distal side and a second tube on the proximal side, and the separation portion is a portion forming a fitting structure in which a proximal portion of the first tube fits in a distal portion of the second tube before the tube is separated into the first tube and the second tube.

(10) The medical tube as described in any one of the

aforementioned paragraphs (1) to (9) is configured such that at least a portion on the distal side as compared with the connection portion is flat in cross-sectional shape.

(11) The medical tube as described in the aforementioned paragraph (10) is configured such that the thickness direction of the flat shape is oriented toward the center of bending of the bent region.

(12) The medical tube as described in any one of the aforementioned paragraphs (1) to (11) is configured such that the whole length of the tube is longer than the whole length of the puncture needle.

(13) The medical tube as described in any one of the aforementioned paragraphs (1) to (11) further includes at least one lumen opening into the proximal end opening, and the implant is to be inserted in the lumen.

(14) A medical tube assembly includes the medical tube as described in any one of the aforementioned paragraphs (1) to (13) and an elongated implant which is inserted in the medical tube.

(15) A puncture needle having a sharp needle tip at the distal end thereof includes a connection portion which is provided at a distal portion of the puncture needle. A proximal portion of a medical tube, which is configured to have an elongated implant inserted therein, is connected to the connection portion.

(16) The puncture needle as described in the aforementioned paragraph (15) is configured such that the connection portion has a cutout where a portion immediately on the proximal side of the needle tip of the puncture needle is partly lost.

(17) The puncture needle as described in the aforementioned paragraph (15) is configured such that the connection portion has a reduced-diameter part where the puncture needle is reduced in outside diameter at a position immediately on the proximal side of the needle tip of the puncture needle.

Advantageous Effect

[0009] According to the present invention, the bent region is prevented from being flattened (pressed) in the living body when the medical tube is inserted into the living body. This ensures that, for example in the case where an implant is preliminarily inserted in the medical tube, the medical tube can be inserted into the living body together with the implant easily and reliably.

[0010] If only the medical tube is pulled out of the living body after the inserting operation, the implant can be left inside the living body and, hence, placed indwelling inside the living body easily and reliably.

[0011] In the state where the medical tube and the puncture needle are connected to each other by way of the connection portions, the puncture needle can be pulled proximally together with the medical tube. This ensures that the medical tube can be easily inserted into and passed through a piercing hole (puncture hole) formed by the puncture needle. In addition, the subsequent indwelling of the implant into the piercing hole (puncture hole) can also be performed easily.

[0012] Where the medical tube has the separation portion, the medical tube can be separated (divided) at the separation portion. This ensures that the medical tube can be easily pulled out of the living body, and, accordingly, the implant can be indwelled into the living body swiftly.

Brief Description of Drawings

[0013]

[FIG. 1]
FIG. 1 is a sectional view for sequentially showing a using method in a first embodiment of a medical tube (medical tube assembly) and a puncture needle according to the present invention.

[FIG. 2]
FIG. 2 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 3]
FIG. 3 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 4]
FIG. 4 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 5]
FIG. 5 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 6]
FIG. 6 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 7]
FIG. 7 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 8]
FIG. 8 is a sectional view for sequentially showing the using method in the first embodiment of the medical tube (medical tube assembly) and the puncture needle.

[FIG. 9]
FIG. 9 is a diagram (side view) as viewed along arrow A in FIG. 1.

[FIG. 10]

FIG. 10 is an enlarged detailed view of region [B] surrounded by an alternate long and short dash line in FIG. 3.

[FIG. 11]

FIG. 11 is a diagram as viewed along arrow C in FIG. 10.

[FIG. 12]

FIG. 12 is a sectional view taken along line D-D in FIG. 4.

[FIG. 13]

FIG. 13 shows diagrams as viewed along arrow E in FIG. 4, wherein (a) shows a state before a separation portion is separated, and (b) shows a state after the separation portion is separated.

[FIG. 14]

FIG. 14 is a longitudinal sectional view showing a second embodiment of the medical tube (medical tube assembly) and the puncture needle according to the present invention.

[FIG. 15]

FIG. 15 is a sectional view for sequentially showing a using method in a third embodiment of the medical tube (medical tube assembly) according to the present invention.

[FIG. 16]

FIG. 16 is a sectional view for sequentially showing the using method in the third embodiment of the medical tube (medical tube assembly).

[FIG. 17]

FIG. 17 is a sectional view for sequentially showing the using method in the third embodiment of the medical tube (medical tube assembly).

Modes for Carrying Out the Invention

[0014] A medical tube, a medical tube assembly and a puncture needle according to the present invention will now be described in detail, referring to some preferred embodiments depicted in the accompanying drawings.

<First Embodiment>

[0015] FIGS. 1 to 8 are sectional views for sequentially illustrating a using method in a first embodiment of a medical tube (medical tube assembly) and a puncture needle according to the present invention; FIG. 9 is a diagram (side view) as viewed along arrow A in FIG. 1; FIG. 10 is an enlarged detailed view of region [B] surrounded by an alternate long and short dash line in FIG. 3; FIG. 11 is a diagram as viewed along arrow C in FIG. 10; FIG. 12 is a sectional view taken along line D-D in FIG. 4; and FIG. 13 shows diagrams as viewed along arrow E in FIG. 4, wherein (a) shows a state before a separation portion is separated, and (b) shows a state after the separation portion is separated. Note that in the following description, the upper side in FIGS. 1 to 9 (and in FIGS. 15 to 17, as well) will be referred to as "upper" or the "upper side," and the lower side in the figures as "lower" or the "lower side," for convenience of description. In addition, the side of a needle tip will be referred to as the "distal side," and the opposite side as the "proximal side."

[0016] A medical tube assembly 1 shown in FIGS. 4 to 6 includes a medical tube (tube) 2, and an implant 8 which is inserted in the medical tube 2. The medical tube assembly 1 is a medical device to be used in treatment of female urinary incontinence. Besides, when treatment of female urinary incontinence is performed, a puncture apparatus 10 is also used together with the medical tube assembly 1, as shown in FIGS. 1 to 4. It can be said that in this embodiment, the medical tube assembly 1 and the puncture apparatus 10 together constitute a "medical device set" for treatment of female urinary incontinence. The configuration of each of the components will now be described below.

[0017] First, the implant 8 will be described.

[0018] The implant 8 is a device which, commonly called "sling," is an implantable device for treatment of female urinary incontinence, specifically, for supporting a urethra 100 in the manner of, for example, pulling the urethra 100 in a direction for spacing away from a vagina 200 when the urethra 100 would otherwise be going to move toward the vagina 200 side (see FIG. 8). The implant 8 includes a band-like (elongated) member which is flexible (see FIGS. 3 to 8).

[0019] The constituent material of the implant 8 is not specifically restricted. Examples of the material applicable here include various resin materials that are biocompatible.

[0020] Note that the implant 8 may be preliminarily inserted (stored or housed) in the medical tube 2 as depicted in FIG. 3, or may be inserted into the medical tube 2 in the course of a procedure. Where the implant 8 is preliminarily inserted in the medical tube 2, it is possible to swiftly perform a procedure. Where the implant 8 is inserted into the medical tube 2 in the course of a procedure, on the other hand, an implant 8 suited to an individual case can be selected in each procedure according to the case. In this embodiment, a case where the implant 8 is preliminarily inserted in the medical tube 2 will be described on a representative basis.

[0021] Now, the puncture apparatus 10 will be described, prior to a description of the medical tube 2.

[0022] As shown in FIGS. 1 to 4 and 9, the puncture apparatus 10 includes a puncture member 3, and a support member 20 which supports the puncture member 3 so that the puncture member 3 is rotatable. Note that the puncture apparatus 10 may further include a bar-shaped urethral-insertion member to be inserted in the urethra 100, and a bar-shaped vaginal-insertion member to be inserted into the vagina 200. These members are preferably supported on and fixed to the support member 20 individually.

[0023] The puncture member 3 includes a puncture needle 31 configured to puncture a living body tissue 700, an axial portion 33, and an interlock portion 32 interlocking the puncture needle 31 and the axial portion

33 to each other.

[0024] The puncture needle 31 has a sharp needle tip 315 at a distal end thereof, and is bent in an arc shape centered on the axial portion 33. In addition, the axis of the puncture needle 31 and the axis of the axial portion 33 are in the relationship of skew lines. This ensures that when the puncture member 3 is rotationally moved about the axial portion 33, the needle tip 315 of the puncture needle 31 is moved along the arc, in a plane orthogonal to the axis of the axial portion 33, namely, in a plane to which the axis of the axial portion 33 is a normal.

[0025] Note that a center angle of the arc of the puncture needle 31 is not particularly limited, and may be appropriately set according to various conditions, in such a manner that when the living body tissue 700 is punctured by the puncture needle 31, the a piercing hole (puncture hole) 500 in an arc shape is formed in the living body tissue 700 as will be described later. Such a center angle is preferably 120 to 270 degrees, more preferably 160 to 230 degrees, and further preferably 180 to 210 degrees.

[0026] While the needle tip 315 of the puncture needle 31 is oriented counterclockwise in FIGS. 1 to 4 in this embodiment, this is not restrictive, and the needle tip 315 may be oriented clockwise in the figures.

[0027] The puncture needle 31 may be formed with a tapered portion 316 where the outside diameter of the puncture needle 31 gradually increases along the proximal direction from the needle tip 315.

[0028] Besides, the puncture needle 31 may be a solid needle or may be a hollow needle.

[0029] The axial portion 33 constitutes a rotation axis for the puncture member 3 (puncture needle 31), and is disposed so as to be rotatable on the support member 20.

[0030] As shown in FIG. 9, the axial portion 33 penetrates the support member 20 along the left-right direction in the figure. A flange 331 and a flange 332 are formed respectively at a distal-side portion and a proximal side portion of the axial portion 33, with the support member 20 interposed therebetween. By the flanges 331 and 332, axial movement of the axial portion 33 relative to the support member 20 is restricted.

[0031] In addition, the axial portion 33 is provided, at an end portion on the side opposite to the puncture needle 31, with a grasping portion 34 as an operating portion for a rotary movement operation of the puncture member 3. The shape of the grasping portion 34 is a rectangular parallelepiped shape in this embodiment. At the time of putting the puncture member 3 into a rotary movement, the grasping portion 34 is grasped with fingers and rotated in a predetermined direction. Note that the shape of the grasping portion 34 is naturally not restricted to the just-mentioned.

[0032] The interlock portion 32 is a portion which interlocks the proximal end of the puncture needle 31 and the axial portion 33.

[0033] The constituent material of the puncture member 3 is not specifically restricted. Examples of the material usable here include various metallic materials such as stainless steel, aluminum or aluminum alloys, titanium or titanium alloys, etc.

[0034] The support member 20 is a member which supports the puncture member 3 so that the puncture member 3 is rotatable. Note that the support member 20 is omitted in FIGS. 1 to 4.

[0035] The support member 20 restricts the position of the puncture member 30 so that when the puncture member 3 rotates and punctures the living body tissue 700, the needle tip 315 of the puncture needle 31 passes between the urethra 100 and the vagina 200. Accordingly, between the urethra 100 and the vagina 200 is formed the arc-shaped piercing hole 500 by the puncture needle 31.

[0036] The constituent material of the support member 20 is not specifically restricted. For example, various resin materials such as polyethylene, polypropylene, etc. can be used.

[0037] Now, the medical tube 2 will be described below.

[0038] As depicted in FIGS. 3 to 5, the medical tube 2 is a tube having a distal end opening 21 where the distal end thereof is open, and a proximal end opening 22 where the proximal end thereof is open.

[0039] In addition, the medical tube 2 is formed therein with a lumen 25 opening into the distal end opening 21 and the proximal end opening 22. The implant 8 can be inserted in the lumen 25. Note that while only one lumen is formed in this embodiment, the number of the lumen(s) is not limited to one, and may be, for example, two or more.

[0040] As shown in FIGS. 3 to 5, the medical tube 2 has a bent region 231 where an intermediate portion in the longitudinal direction thereof is bent in an arc shape. The medical tube 2 is rigid at least at the bent region 231. The term "rigid" used here means an extent of rigidity such that the bent region 231 can maintain its arc-shaped bent state by itself. Besides, the degree of bending (curvature) of the bent region 231 is preferably comparable to or lower than that of the puncture needle 31 of the puncture apparatus 10.

[0041] The just-mentioned configuration ensures that when the medical tube 2 is inserted into the piercing hole 500 formed by the puncture apparatus 10, the bent region 231 is prevented from being flattened (pressed) inside the piercing hole 500, and the bent region 231 can easily follow the bent shape of the piercing hole 500. Consequently, an operation of inserting the medical tube 2 into the piercing hole 500 (living body) together with the implant 8 can be carried out easily and reliably. Besides, with the medical tube 2 separated (as will be described later) after the inserting operation, the implant 8 can be indwelled in the piercing hole 500 easily and assuredly (see FIG. 6).

[0042] As illustrated in FIG. 12, the cross-sectional shape of the bent region 231, or the cross-sectional shape of that portion of the medical tube 2 which is on the more distal side than the vicinity of the proximal end

opening 22 (connection portion 232), is a somewhat flat shape, specifically, an elliptic shape. This cross-sectional shape ensures that in the case where the band-shaped implant 8 is preliminarily inserted in the lumen 25, the inserting operation can be carried out easily. It also ensures that it is possible to form a space for reliable insertion of the implant 8 in the piercing hole 500. It further ensures that the orientation of the implant 8 can be restricted.

[0043] Note that the cross-sectional shape of the bent region 231 may be other shape than the somewhat flat shape, for example, a circular shape.

[0044] As shown in FIG. 12, the thickness direction (minor-diameter direction) of the somewhat flat shape is oriented toward the center of bending (curvature) O of the bent region 231. This configuration contributes more to easy insertion of the medical tube 2 into the piercing hole 500, as compared with the case where the width direction (major-diameter direction) of the somewhat flat shape is oriented toward the center of bending (curvature) O.

[0045] As depicted in FIGS. 3 and 4, the medical tube 2 is provided, in the vicinity of the proximal end opening 22, with the connection portion (tube-side connection portion) 232 into which the puncture needle 31 of the puncture member 3 is to be inserted and connected from the needle tip 315 side. On the other hand, the puncture needle 31 is provided at its distal end portion with a connection portion (puncture needle side connection portion) 317 to which the connection portion 232 (proximal end portion) of the medical tube 2 is to be connected.

[0046] As shown in FIGS. 10 and 11, the connection portion 232 of the medical tube 2 has a small piece 232a at a portion on an outer side with respect to the bend. The small piece 232a is configured by forming a roughly U-shaped slit 232b that penetrates the tube wall of the medical tube 2, and bending the portion surrounded by the slit 232b toward the inner side. Note that the slit 232b is inverted U-shaped in FIG. 11; in other words, the U-shape is opening toward the proximal side (toward the lower side in FIG. 11).

[0047] In addition, the connection portion 317 of the puncture needle 31 has a cutout 317a where the connection portion 317 is partly lost. The cutout 317a is located immediately on the proximal side of, and on the outer side with respect to the bend of, the needle tip 315. The cutout 317a is formed in a wedge-like shape such that the depth thereof gradually decreases along the proximal direction (along the downward direction in FIG. 10).

[0048] As illustrated in FIGS. 10 and 11, in a state where the connection portion 232 of the medical tube 2 and the connection portion 317 of the puncture needle 31 are connected to each other (this state will hereinafter be referred to as the "connected state"), the small piece 232a of the connection portion 232 engages the cutout 317a of the connection portion 317. This ensures that the connected state is maintained reliably, in other words, an unintended canceling of the connected state is prevented.

[0049] As shown in FIGS. 3 and 4, by rotating the puncture member 3 clockwise in the figures in the connected state, the medical tube 2 can be pulled in that direction. By this operation, the medical tube 2 can be easily inserted into and passed through the piercing hole 500, and the subsequent indwelling of the implant 8 into the piercing hole 500 can be performed easily.

[0050] Note that the connection portion 232 may be rigid like the bent region 231 or may, instead, be soft or flexible.

[0051] As illustrated in FIGS. 6 and 13(b), the medical tube 2 is so configured that it can be separated (divided), at an intermediate portion in the longitudinal direction thereof, into a first tube 233 on the distal side and a second tube 234 on the proximal side. This separation (division) makes it possible to swiftly draw the medical tube 2 out of the piercing hole 500 and, therefore, to leave only the implant 8 indwelling in the piercing hole 500.

[0052] As shown in FIGS. 3 to 5, a separation portion 235 for this separation (division) is located at a central portion in the longitudinal direction of the bent region 231. This enables the urethra 100 to be suitably supported by the implant 8 upon separation (division) of the medical tube 2 at the separation portion 235, as depicted in FIG. 6.

[0053] Preferably, markers 27 for grasping of the central portion in the longitudinal direction of the bent region 231 are provided respectively at a distal portion and a proximal portion of the medical tube 2 (see FIG. 5). The markers 27 enable reliable grasping of the position of the central portion in the longitudinal direction of the bent region 231, namely, the position of the separation portion 235. Note that while the markers 27 are provided respectively at both the distal portion and the proximal portion of the medical tube 2 in this embodiment, this configuration is not restrictive, and, for example, a marker may only be provided at one of the distal portion and the proximal portion of the medical tube 2.

[0054] As depicted in FIG. 13(a), before the separation (division) of the medical tube 2 into the first tube 233 and the second tube 234, the separation portion 235 constitutes a fitting structure in which a proximal end portion 236 of the first tube 233 fits inside a distal end portion 237 of the second tube 234. This ensures that when the medical tube 2 is pulled from both sides thereof, the fitting state between the proximal end portion 236 of the first tube 233 and the distal end portion 237 of the second tube 234 can be canceled in an assured manner. By this canceling of the fit, the medical tube 2 can be easily separated at the separation portion 235 into the first tube 233 and the second tube 234.

[0055] Note that the proximal end portion 236 of the first tube 233 is formed with a gradually decreasing width portion 238 where the width thereof gradually decreases along proximally. This ensures that when the medical tube 2 is to be left in the state as depicted in FIG. 13(a), the proximal end portion 236 of the first tube 233 can be easily inserted into the distal end portion 237 of the sec-

ond tube 234, resulting in the fitting state between the end portions.

[0056] In addition, the outside width (maximum width) w_1 of the proximal end portion 236 of the first tube 233 is equal to or slightly smaller than the inside width w_2 of the distal end portion 237 of the second tube 234. This permits easier insertion of the proximal end portion 236 of the first tube 233 into the distal end portion 237 of the second tube 234.

[0057] As aforementioned, the fitting structure between the proximal end portion 236 of the first tube 233 and the distal end portion 237 of the second tube 234 is such that the proximal end portion 236 is located on the inner side and is located on the outer side of the distal end portion 237. In this case, at the separation portion 235, specifically, in the boundary area between the proximal end portion 236 and the distal end portion 237, there is formed a step 239 where the width of the medical tube 2 is reduced stepwise along the distal direction (see FIG. 13(a)). Since the medical tube 2 is inserted into the piercing hole 500, starting from the proximal end thereof, it is preferable that the step 239 is formed in the just-mentioned fashion.

[0058] Note that the medical tube 2 preferably has a whole length which is longer than the whole length of the puncture needle 31. Accordingly, the medical tube 2 is longer than the whole length of the piercing hole 500 formed by the puncture needle 31, so that both end portions of the medical tube 2 protrude from the piercing hole 500 in a state where the medical tube 2 is inserted in and passed through the piercing hole 500 as illustrated in FIGS. 4 and 5. When separating the medical tube 2 into the first tube 233 and the second tube 234 on the proximal side and pulling these tubes out of the piercing hole 500, the pulling-out operation can be performed by grasping the protruding end portions.

[0059] The constituent material of the medical tube 2 is not specifically restricted. Examples of the material applicable here include polyolefins such as polyethylene, polypropylene, ethylene-vinyl acetate copolymer, etc., modified polyolefins, polyamides (e.g., nylon 6, nylon 46, nylon 66, nylon 610, nylon 612, nylon 11, nylon 12, nylon 6-12, and nylon 6-66), thermoplastic polyimides, liquid crystal polymers such as aromatic polyesters, etc., polyphenylene oxide, polyphenylene sulfide, polycarbonate, polymethyl methacrylate, polyethers, polyether-ether ketone, polyether-imides, polyacetal, various thermoplastic elastomers based on styrene, polyolefin, polyvinyl chloride, polyurethane, polyester, polyamide, polybutadiene, trans-polyisoprene, fluoro-rubber, chlorinated polyethylene or the like, and copolymers, polymer blends, polymer alloys, etc. containing the just-mentioned polymers. These materials may be used either singly or as a mixture of two or more of them.

[0060] Now, an exemplary method of using the medical tube assembly 1 and the puncture apparatus 10 will be described below, referring to FIGS. 1 to 8.

[0061]

[1] First, as shown in FIG. 1, the puncture apparatus 10 is mounted onto a patient's body surface 600. The mounting position in this instance can be a position suitable for supporting the urethra 100 by the implant 8 that is going to be implanted.

[2] Next, with the grasping portion 34 of the puncture apparatus 10 grasped by one hand, the puncture member 3 is rotated counterclockwise in FIG. 2, as shown in the figure. Upon this rotation, the puncture needle 31 is moved with the axial portion 33 as a rotation center, to sequentially pass (in other words, puncture) an inguinal region on the left side in the figure (or a region in the vicinity of the inguinal region) of the patient's body surface 600, an obturator foramen 400a in a pelvis 300, a region between the urethra 100 and the vagina 200, an obturator foramen 400b in the pelvis 300, and an inguinal region on the right side in the figure (or a region in the vicinity of the inguinal region) of the body surface 600. As a result of the puncturing, the piercing hole 500 that penetrates the living body tissue 700 from the left-side inguinal region of the body surface 600 to the right-side inguinal region of the body surface 600 is formed in the living body tissue 700. Besides, the puncture needle 31 has its connection portion 317 protruding from the right-side inguinal region of the body surface 600.

[3] Subsequently, the medical tube assembly 1 with the implant 8 inserted in the medical tube 2 is prepared. As shown in FIG. 3, the connection portion 317 of the puncture needle 31 is inserted into the connection portion 232 of the medical tube 2, and the connection portions 317 and 232 are connected to each other. As a result, the medical tube 2 and the puncture needle 31 are in a connected state. In this connected state, the small piece 232a of the connection portion 232 is in engagement with the cutout 317a in the connection portion 317, as aforementioned. By the engagement, the connected state can be maintained reliably.

[4] Next, with the grasping portion 34 of the puncture apparatus 10 grasped by one hand, the puncture member 3 is rotated in the direction opposite to the above-mentioned, namely, rotated clockwise in FIG. 4, as shown in the figure. Upon this rotation, the puncture member 3 is pulled out of the piercing hole 500, and, this time, the medical tube assembly 1 (medical tube 2) is inserted into and passed through the piercing hole 500. The medical tube assembly 1 is now in a state in which its distal-side portion is protruding from the body surface 600 on the side of the obturator foramen 400b, whereas its proximal-side portion is protruding from the body surface 600 on the side of the obturator foramen 400a.

[5] Subsequently, as shown in FIG. 5, the puncture member 3 of the puncture apparatus 10 is taken away from the body surface 600 together with the support member 20.

[6] Next, of the medical tube assembly 1, the portion protruding from the body surface 600 on the side of the obturator foramen 400b is grasped by one hand, while the portion protruding from the body surface 600 on the side of the obturator foramen 400a is grasped by the other hand, and the grasped portions are pulled in opposite directions, as illustrated in FIG. 6. As a result, the medical tube 2 is separated (divided) into the first tube 233 and the second tube 234 by virtue of the separation portion 235.

[7] Subsequently, the first tube 233 and the second tube 234 are individually pulled out of the piercing hole 500, whereon the implant 8 is left inserted in and passed through the piercing hole 500, as shown in FIG. 7. The implant 8 is now in a state in which its distal-side portion is protruding from the body surface 600 on the side of the obturator foramen 400b, whereas its proximal-side portion is protruding from the body surface 600 on the side of the obturator foramen 400a. Then, the distal-side portion and the proximal-side portion of the implant 8 are pulled with respective predetermined forces. As a result, a tension is generated on the implant 8, whereby the urethra 100 is pulled in a direction for spacing away from the vagina 200 and is supported by the implant 8 from below.

[8] Next, as shown in FIG. 8, unnecessary portions of the implant 8 are cut away, and predetermined wound closure and the like are conducted, to finish the procedure.

[0062] In the above-described procedure, or treatment of urinary incontinence, at the time of inserting the implant 8 into the piercing hole 500 and indwelling the implant 8 in situ, the implant 8 has preliminarily been housed in the medical tube 2 and is inserted into the piercing hole 500 together with the medical tube 2. The medical tube 2 is rigid, at least at its bent region 231, as aforementioned. Therefore, the medical tube 2 is prevented from being unintendedly deformed through being flattened or pressed by the living body tissue 700 when situated in the piercing hole 500. Accordingly, the operation of inserting the implant 8 (together with the medical tube 2) into the piercing hole 500 can be carried out easily and reliably.

[0063] In addition, in the present procedure, the medical tube 2 can be easily pulled out of the piercing hole 500 through the separation thereof, after the implant 8 is inserted into the piercing hole 500 together with the medical tube 2. Consequently, the implant 8 is indwelled in the piercing hole 500 in a reliable manner.

[0064] Besides, in the connected state, the puncture needle 31 can be pulled proximally together with the medical tube 2. This ensures that the medical tube 2 can easily be inserted into and passed through the piercing hole 500, and the subsequent indwelling of the implant 8 into the piercing hole 500 can also be carried out easily.

<Second Embodiment>

[0065] FIG. 14 is a longitudinal sectional view showing a second embodiment of the medical tube (medical tube assembly) and the puncture needle according to the present invention.

[0066] Referring to this figure, the second embodiment of the medical tube, medical tube assembly and puncture needle according to the present invention will be described below. In the following, description will be mainly made of differences of the second embodiment from the aforementioned first embodiment, and the same or similar items to those described above will be omitted from the description.

[0067] This embodiment is the same as the first embodiment above, except for differences in the configurations of connection portions of the medical tube and the puncture needle.

[0068] As depicted in FIG. 14, in this embodiment, a connection portion 232 of a medical tube 2A has a reduced-diameter part 232c where the medical tube 2A is reduced in inside diameter. The reduced-diameter part 232c is formed, for example, by heat shrinkage of that portion of the medical tube 2A which is to be the reduced-diameter part 232c.

[0069] In addition, a connection portion 317 of a puncture needle 31 of a puncture member 3A has a reduced-diameter part 317b where the puncture needle 31 is reduced in outside diameter at a position immediately on the proximal side of a tapered portion 316 of a needle tip 315. The reduced-diameter part 317b is formed, for example, by cutting that portion of the puncture needle 31 which is to be the reduced-diameter part 317b.

[0070] In a connected state, the reduced-diameter part 232c of the connection portion 232 of the medical tube 2A is in engagement with the reduced-diameter part 317b of the connection portion 317 of the puncture needle 31. By this engagement, the connected state is maintained securely. Consequently, the medical tube 2A can be made to pass a piercing hole 500, following the puncture member 3A, as aforementioned.

<Third Embodiment>

[0071] FIGS. 15 to 17 are sectional views for sequentially illustrating a using method in a third embodiment of the medical tube (medical tube assembly) according to the present invention.

[0072] The third embodiment of the medical tube, medical tube assembly and puncture needle according to the present invention will be described below, referring to these figures. In the following, description will be mainly made of differences of the third embodiment from the above embodiments, and the same or similar items to those described above will be omitted from the description.

[0073] This embodiment is the same as the first embodiment above, except that the separation portion is

omitted from the medical tube.

[0074] As shown in FIGS. 15 and 16, a medical tube 2B in this embodiment has a configuration wherein a separation portion, such as the separation portion 235 possessed by the medical tube 2 in the first embodiment above, is omitted.

[0075] Besides, a distal portion 81 of an implant 8 is preliminarily set protruding from a distal end opening 21 of the medical tube 2B.

[0076] An exemplary method of using a medical tube assembly 1 possessing the medical tube 2B configured as above will be described, referring to FIGS. 15 to 17. Note that this using method is the same as the using method in the first embodiment above in operations [1] to [3] and operations [7] and [8], but is different from the using method in the first embodiment in operations [4] to [6]. Here, the different operations will be described.

[0077] [4'] After the operation [3] described above, the medical tube assembly 1 with the implant 8 inserted in the medical tube 2B is prepared. As aforementioned, the distal portion 81 of the implant 8 is protruding from the distal end opening 21 of the medical tube 2B.

[0078] After a connected state is established, the puncture member 3 is rotated clockwise in FIG. 15, as shown in the figure. By this rotation, the puncture member 3 is pulled out of the piercing hole 500, and, this time, the medical tube assembly 1 (medical tube 2B) is inserted into and passed through the piercing hole 500. Besides, the medical tube assembly 1 is in a state where its distal-side portion is protruding from the body surface 600 on the side of the obturator foramen 400b, whereas its proximal-side portion is protruding from the body surface 600 on the side of the obturator foramen 400a. Even in this state, the distal portion 81 of the implant 8 is protruding from the distal end opening 21 of the medical tube 2B.

[0079] [5'] Next, as shown in FIG. 16, the puncture member 3 of the puncture apparatus 10 is taken away from the body surface 600 together with the support member 20.

[0080] [6'] Subsequently, as depicted in FIG. 17, with the distal portion 81 of the implant 8 grasped by one hand, then, keeping this state, a proximal portion of the medical tube 2B is grasped by the other hand, and the proximal portion is drawn proximally until the medical tube 2B is pulled out of the piercing hole 500. As a result, the implant 8 is left inserted in and passed through the piercing hole 500.

[0081] Thereafter, the operations [7] and [8] are carried out sequentially.

[0082] Note that while in the medical tube 2B the distal portion 81 of the implant 8 is preliminarily set protruding from the distal end opening 21, this is not restrictive. The distal portion 81 may be set retracted to the depth side from the distal end opening 21. In this case, it is preferable for the medical tube 2B, for example, to be so configured that its distal portion is separable. Such a configuration ensures that upon separation of the distal portion, the distal portion 81 of the implant 8 protrudes from the medical tube 2B. By separating the distal portion after the operation [5'], then, it is possible to carry out the operation [6'] in an assured manner.

[0083] While the medical tube, medical tube assembly and puncture needle according to the present invention have been described above referring to the embodiments shown in the drawings, the present invention is not limited to the embodiments. Each of the components of the medical tube, medical tube assembly and puncture needle may be replaced with one of an arbitrary configuration that is able to function in an equivalent manner. Besides, arbitrary structures or configurations may be added to the aforementioned.

[0084] Each of the medical tube, the medical tube assembly and the puncture needle disclosed here may be a combination of arbitrary two or more configurations (features) of the above embodiments.

[0085] While in the above embodiments the bent region of the medical tube maintains its state of being bent in an arc shape by its own rigidity, this is not restrictive. The bent state of the bent region may be maintained, for example, by a method in which a rigid stylet or the like having a bent region bent in an arc shape is inserted in the medical tube.

[0086] Furthermore, the separation portion of the medical tube may include a perforation.

Industrial Applicability

[0087] The medical tube according to the present invention is a medical tube in which to insert an elongated implant. The medical tube is composed essentially of a tube having a distal end opening where the tube is open at its distal end, and a proximal end opening where the tube is open at its proximal end. The tube has a bent region where an intermediate portion in the longitudinal direction of the tube is bent and the bent state is maintained. The tube also has a connection portion which is provided at the proximal end opening and to which a puncture needle having a sharp needle tip at its distal end is connected from the needle tip side. By use of the medical tube, therefore, an operation of inserting an implant into a living body and indwelling the implant inside the living body can be carried out easily and reliably.

[0088] Accordingly, the medical tube assembly according to the present invention has industrial applicability.

Description of Reference Symbols

[0089]

1 Medical tube assembly
10 Puncture apparatus
2,2A, 2B Medical tube (tube)
21 Distal end opening
22 Proximal end opening
231 Bent region

232 Connection portion (Tube-side connection portion)
232a Small piece
232b Slit
232c Reduced-diameter part
233 First tube
234 Second tube
235 Separation portion
236 Proximal end portion
237 Distal end portion
238 Gradually decreasing width portion
239 Step
25 Lumen
27 Marker
3, 3A Puncture member
31 Puncture needle
315 Needle tip
316 Tapered portion
317 Connection portion (Puncture needle side connection portion)
317a Cutout
317b Reduced-diameter part
32 Interlock portion
33 Axial portion
331, 332 Flange
34 Grasping portion
8 Implant
81 Distal portion
20 Support member
100 Urethra
200 Vagina
300 Pelvis
400a, 400b Obturator foramen
500 Piercing hole (Puncture hole)
600 Body surface
700 Living body tissue
O Center of bending
w_1, w_2 Width

Claims

1. A medical tube configured to have an elongated implant inserted therein, the medical tube comprising a tube having a proximal end opening where the tube is open at a proximal end thereof,
the tube including

a bent region where an intermediate portion in a longitudinal direction of the tube is bent and where a bent state is maintained, and
a connection portion which is provided near the proximal end opening and to which a puncture needle having a sharp needle tip at a distal end thereof is connected from the needle tip side.

2. The medical tube according to claim 1,
wherein the tube is rigid at least at the bent region.

3. The medical tube according to claim 1 or 2,
wherein the connection portion has a small piece formed by forming at least one slit that penetrates a tube wall of the tube, and bending a portion surrounded by the slit toward an inner side.

4. The medical tube according to claim 1 or 2,
wherein the connection portion has a reduced-diameter part where the tube is reduced in inside diameter.

5. The medical tube according to any one of claims 1 to 4,
wherein the bent region is bent in an arc shape.

6. The medical tube according to any one of claims 1 to 5, further comprising
a separation portion permitting the tube to be separated at an intermediate position in the longitudinal direction of the tube.

7. The medical tube according to claim 6,
wherein the separation portion is disposed at a central portion in a longitudinal direction of the bent region.

8. The medical tube according to claim 7,
wherein the tube is provided with a marker for grasping of a position of the central portion in the longitudinal direction of the bent region.

9. The medical tube according to any one of claims 6 to 8,
wherein the tube is separated by virtue of the separation portion into a first tube on a distal side and a second tube on a proximal side, and
the separation portion is a portion forming a fitting structure in which a proximal portion of the first tube fits in a distal portion of the second tube before the tube is separated into the first tube and the second tube.

10. The medical tube according to any one of claims 1 to 9,
wherein at least a portion on a distal side as compared with the connection portion is flat in cross-sectional shape.

11. The medical tube according to claim 10,
wherein a thickness direction of the flat shape is oriented toward a center of bending of the bent region.

12. The medical tube according to any one of claims 1 to 11,
wherein the tube has a whole length longer than a whole length of the puncture needle.

13. The medical tube according to any one of claims 1

to 11, further comprising
at least one lumen opening into the proximal end opening,
wherein the implant is to be inserted in the lumen.

14. A medical tube assembly comprising:

the medical tube according to any one of claims 1 to 13; and
an elongated implant which is inserted in the medical tube.

15. A puncture needle having a sharp needle tip at a distal end thereof, the puncture needle comprising
a connection portion which is provided at a distal portion of the puncture needle and to which a proximal portion of a medical tube configured so as to have an elongated implant inserted therein is connected.

16. The puncture needle according to claim 15,
wherein the connection portion has a cutout where a portion immediately on a proximal side of the needle tip of the puncture needle is partly lost.

17. The puncture needle according to claim 15,
wherein the connection portion has a reduced-diameter part where the puncture needle is reduced in outside diameter at a position immediately on a proximal side of the needle tip of the puncture needle.

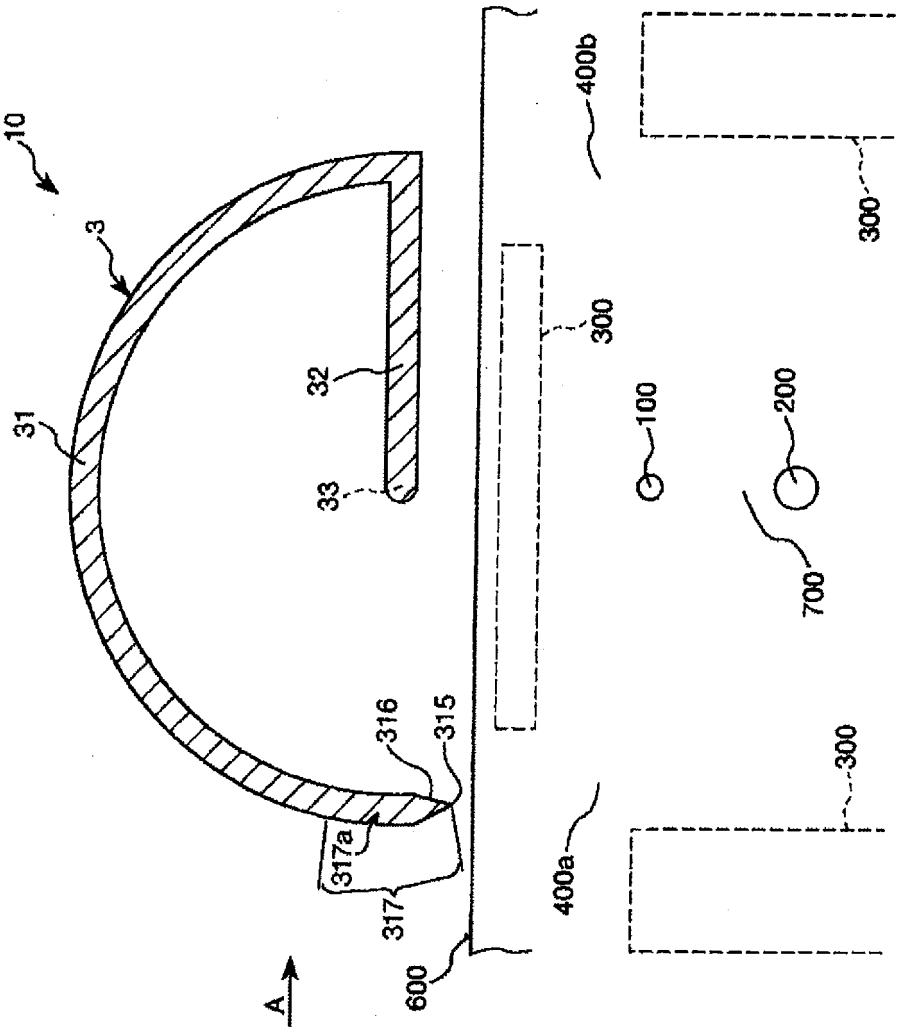
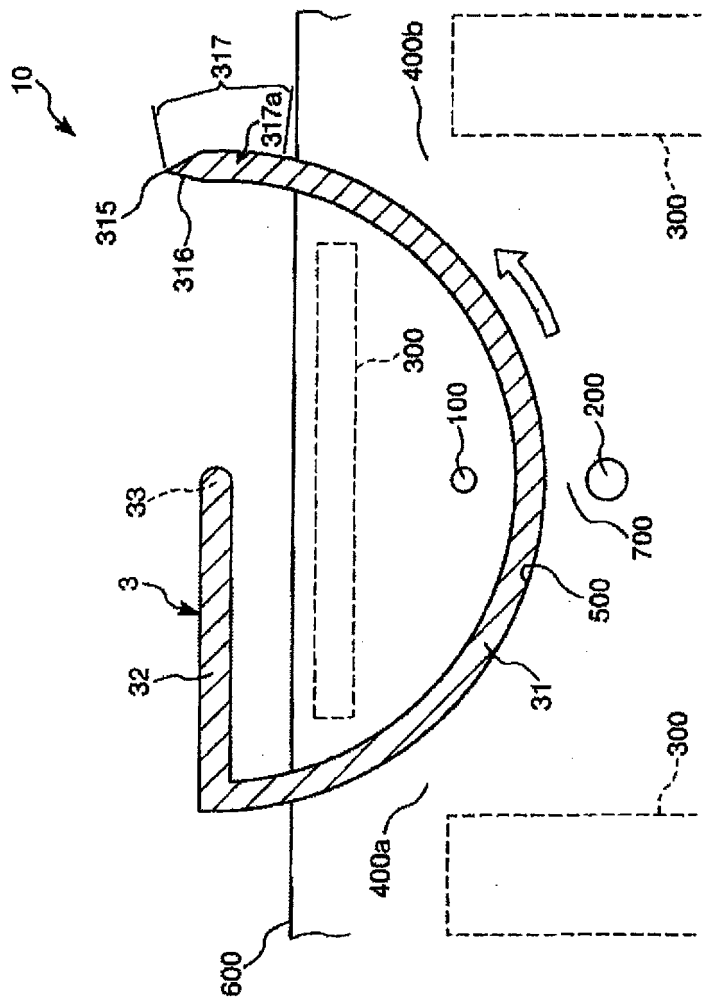

10
3
31
32
33
316
315
317a
317
600
A
400b
400a
300
300
300
100
200
700

FIG. 1


10
317
317a
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400b
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100
200
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500
33
3
32
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400a
600

FIG. 2

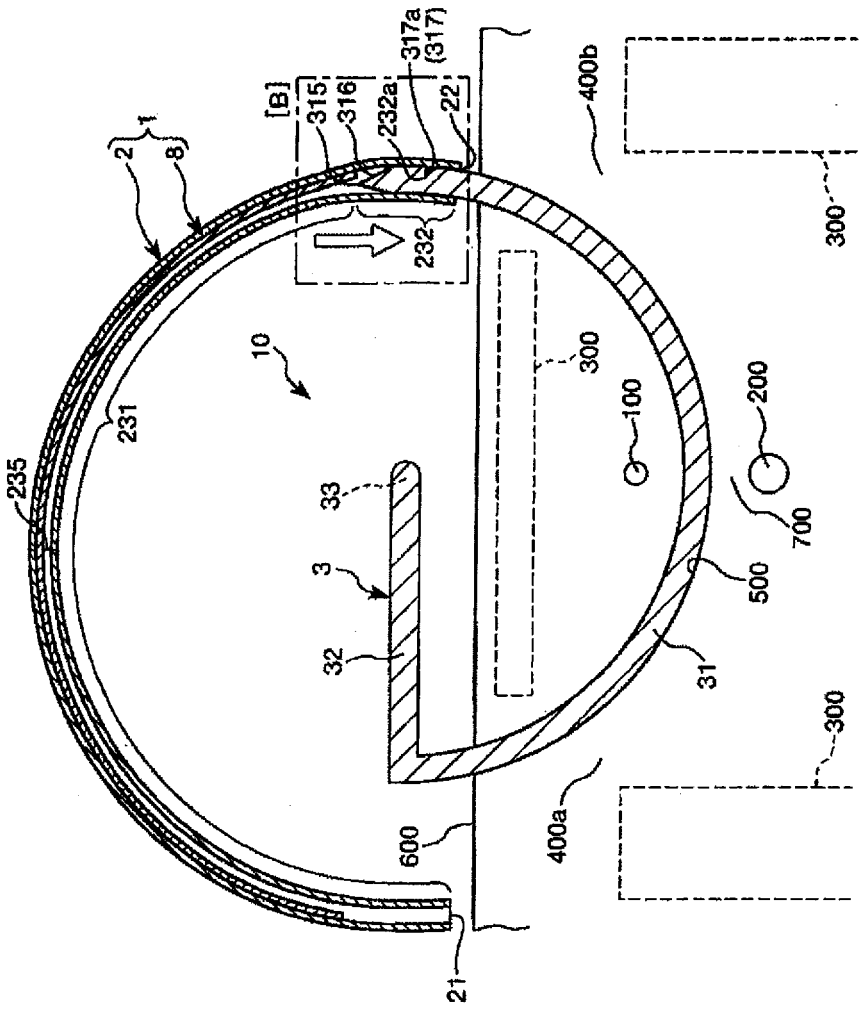
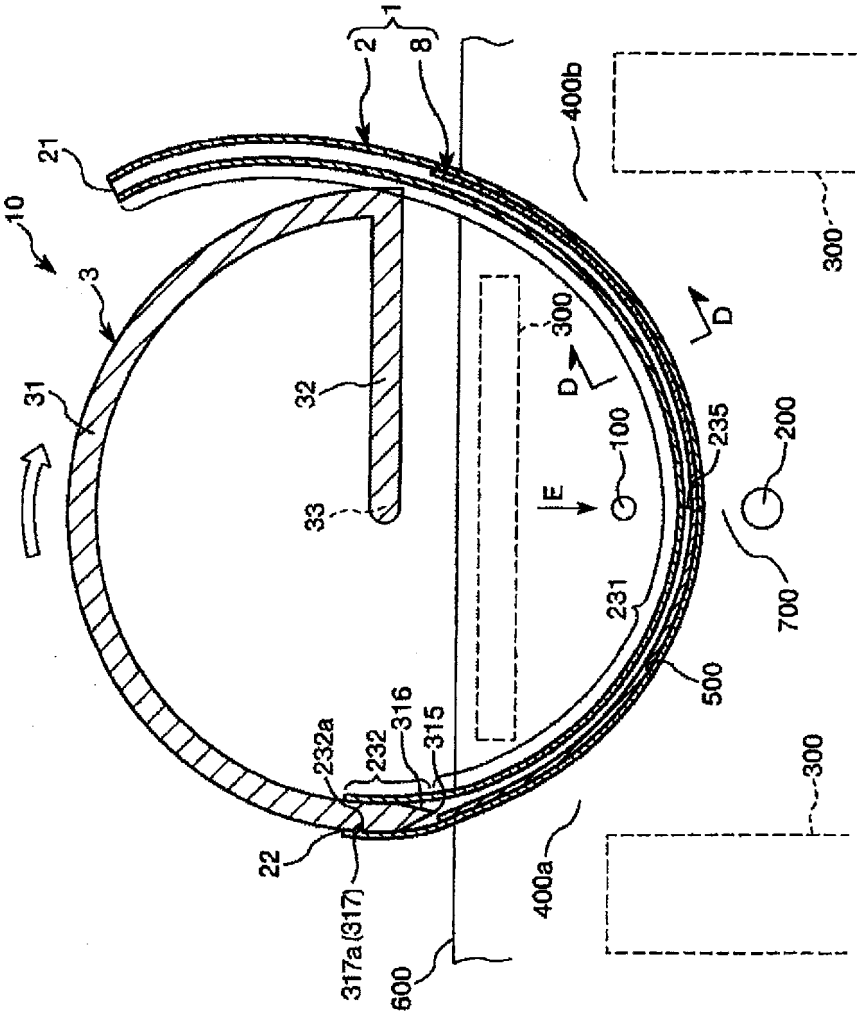

[B]
315
316
232a
317a
(317)
22
232
1
2
8
231
235
10
33
3
32
21
600
400a
400b
300
100
200
700
500
31

FIG. 3


1
2
8
21
10
3
31
32
33
400b
300
D
D
300
100
E
235
200
700
231
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316
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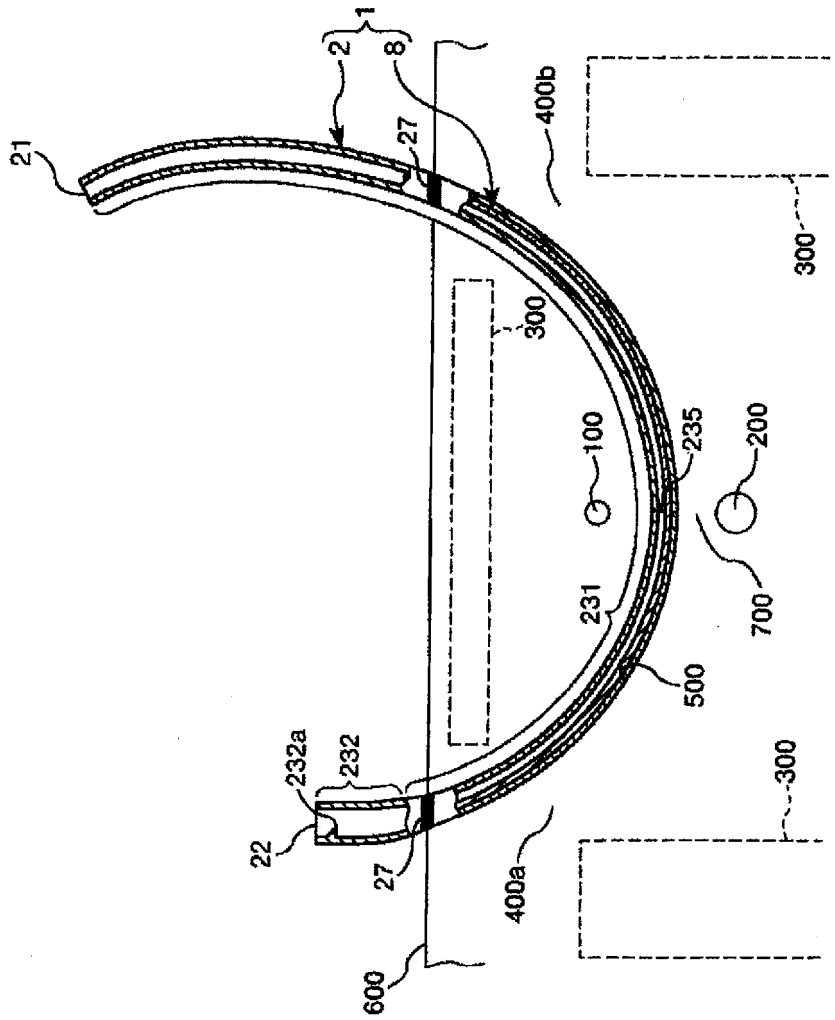
232a
232
22
317a (317)
600
400a
300

FIG. 4


1
2
8
21
27
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300
100
235
200
231
700
500
232a
232
22
27
400a
300
600

FIG. 5

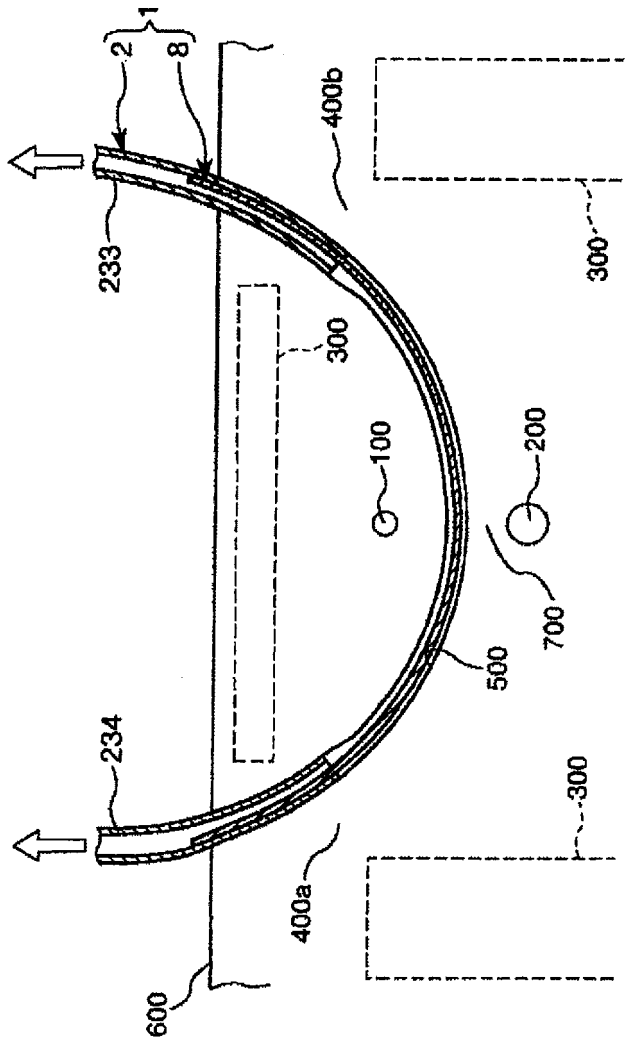


FIG.6

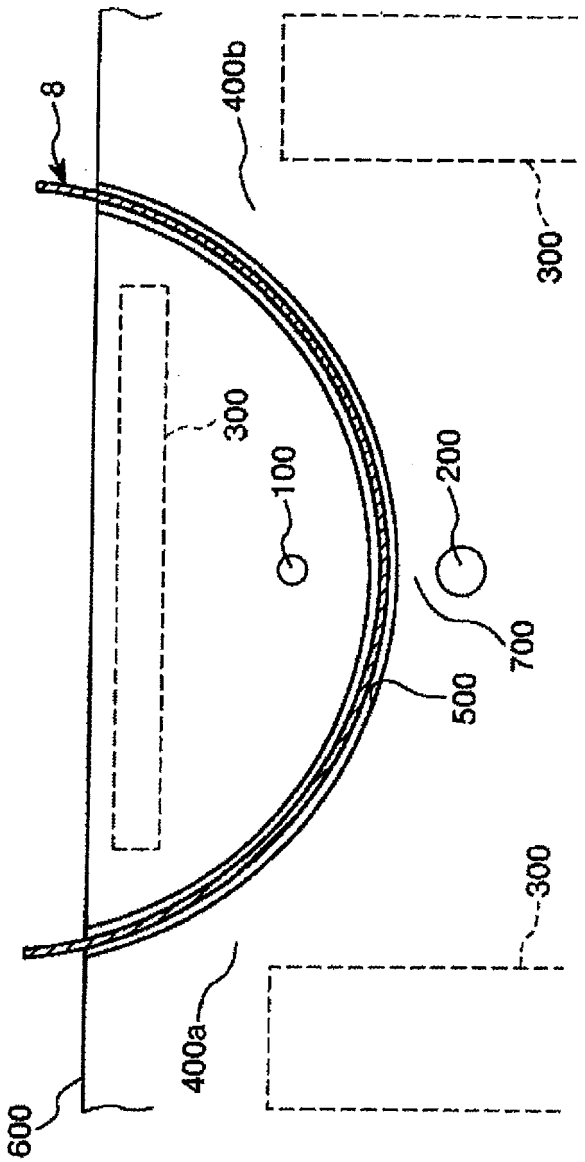


FIG. 7

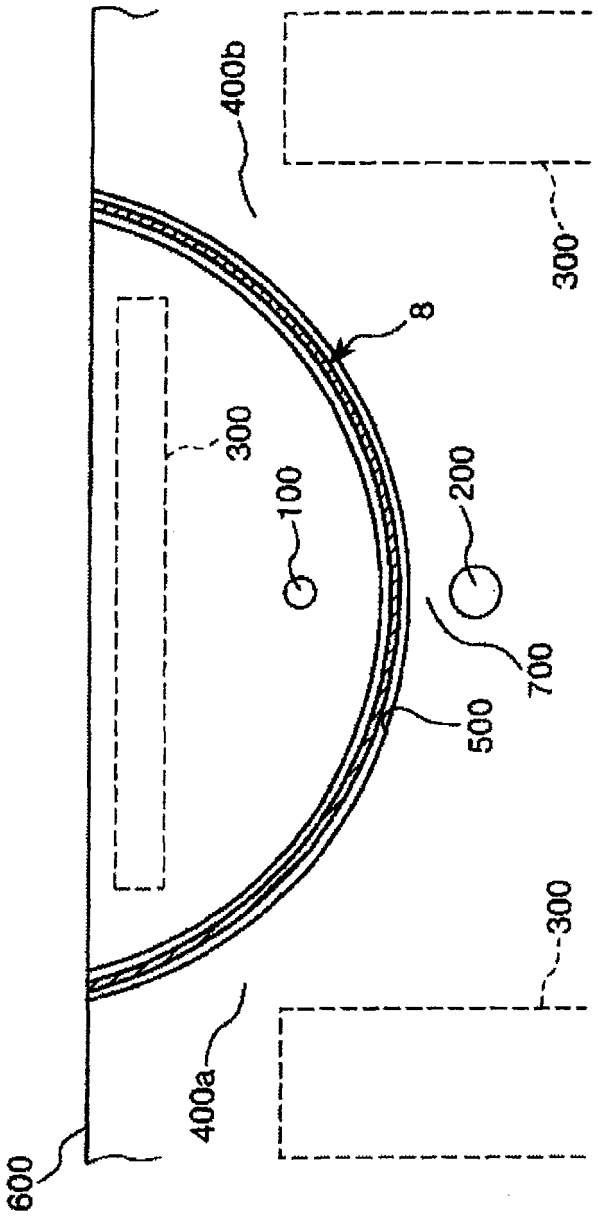


FIG. 8

FIG. 9

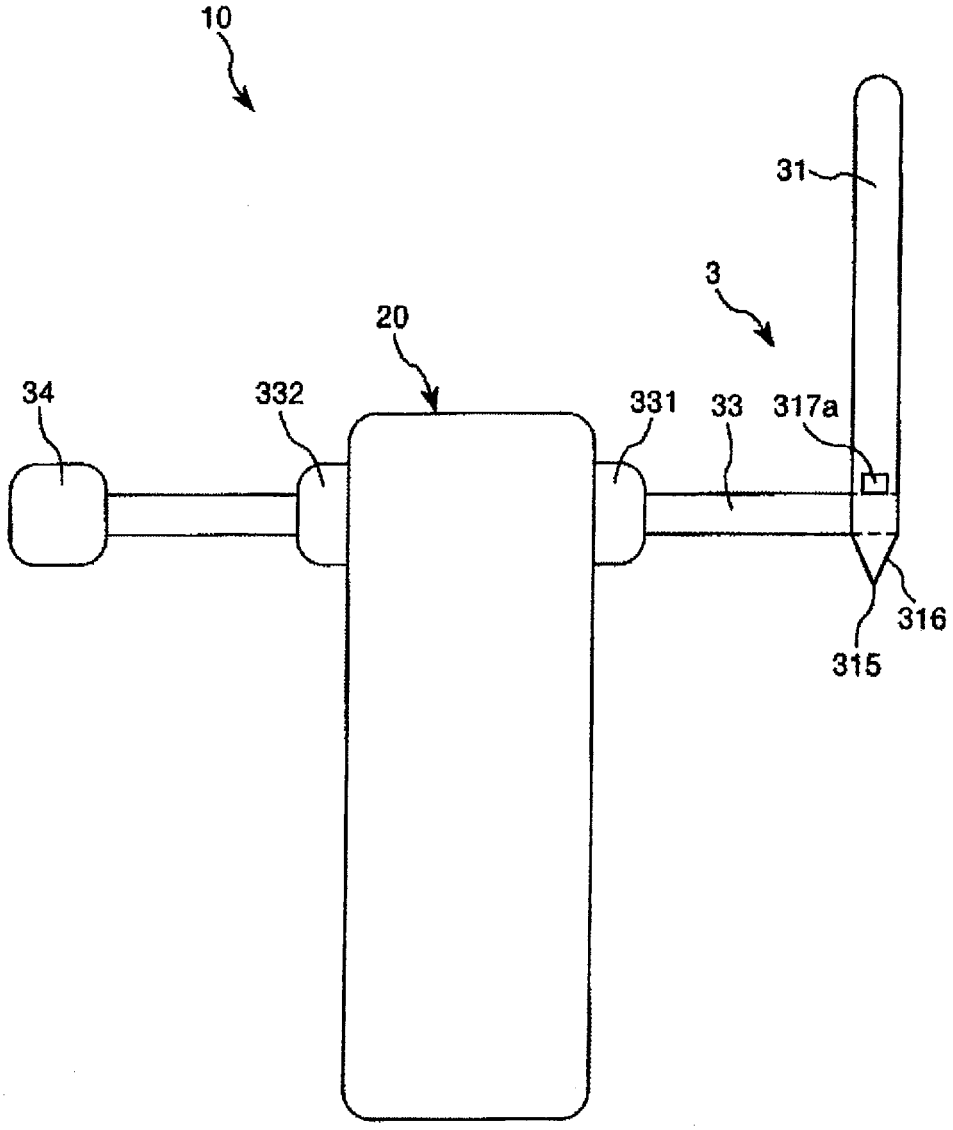


FIG. 10

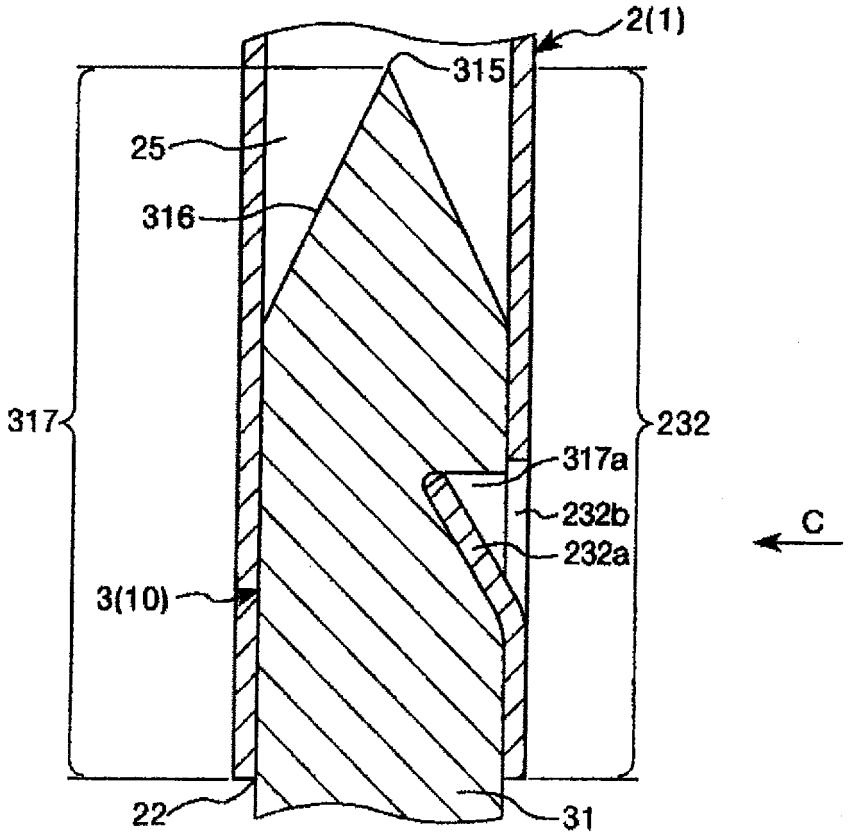


FIG. 11

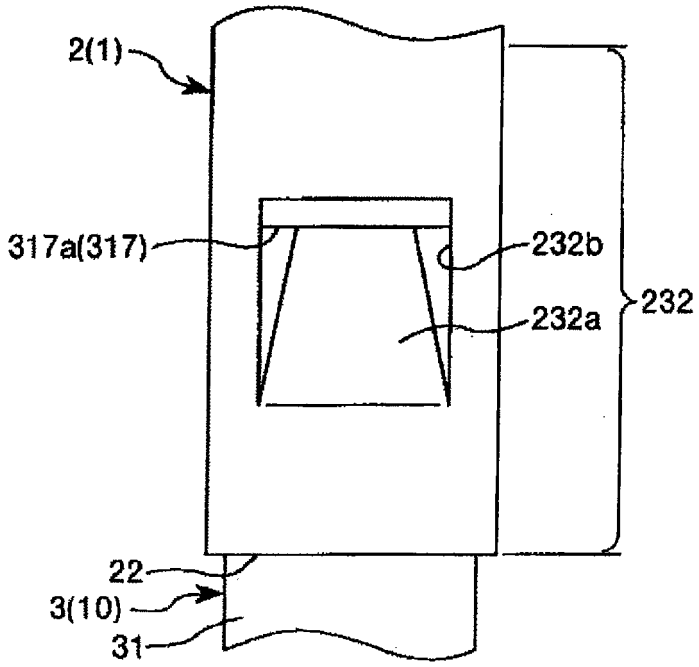


FIG. 12

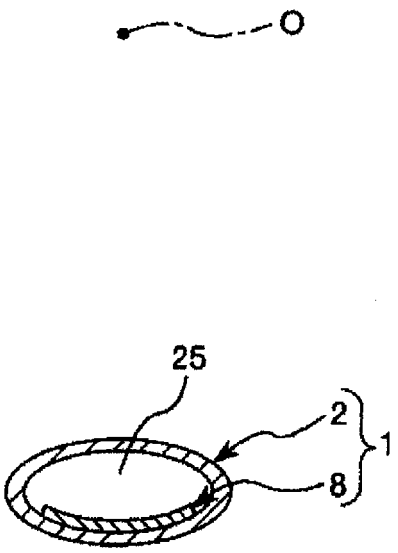


FIG. 13

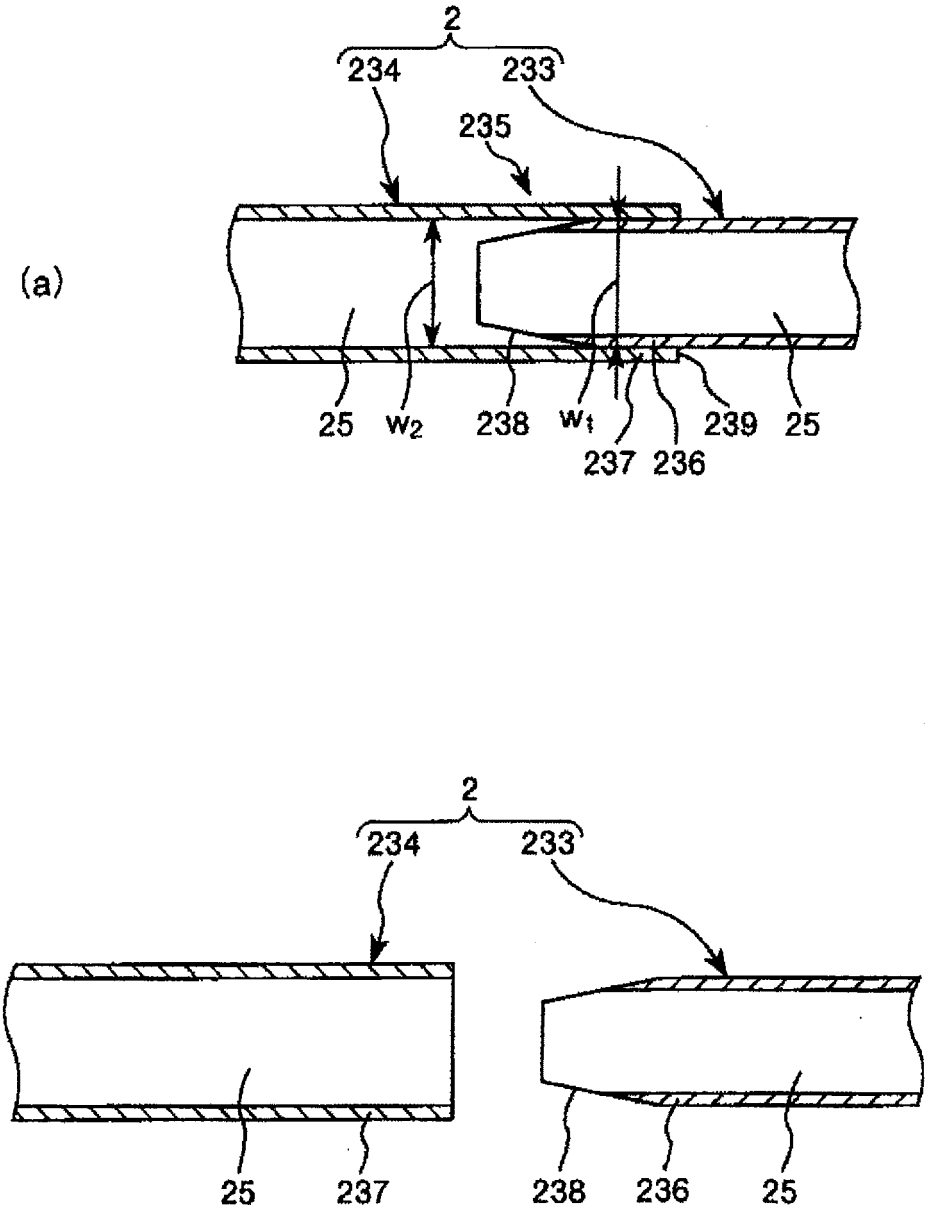
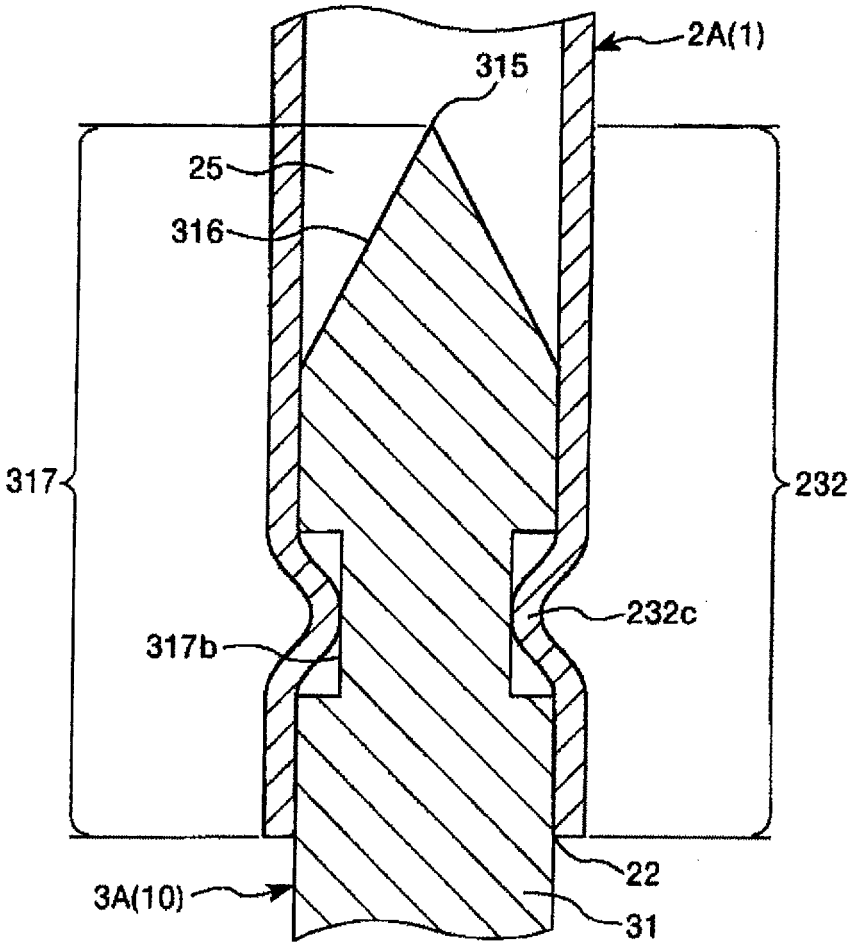

(a)
2
234
233
235
25
w_2
238
w_1
237
236
239
25
(b)
2
234
233
25
237
238
236
25

FIG. 14



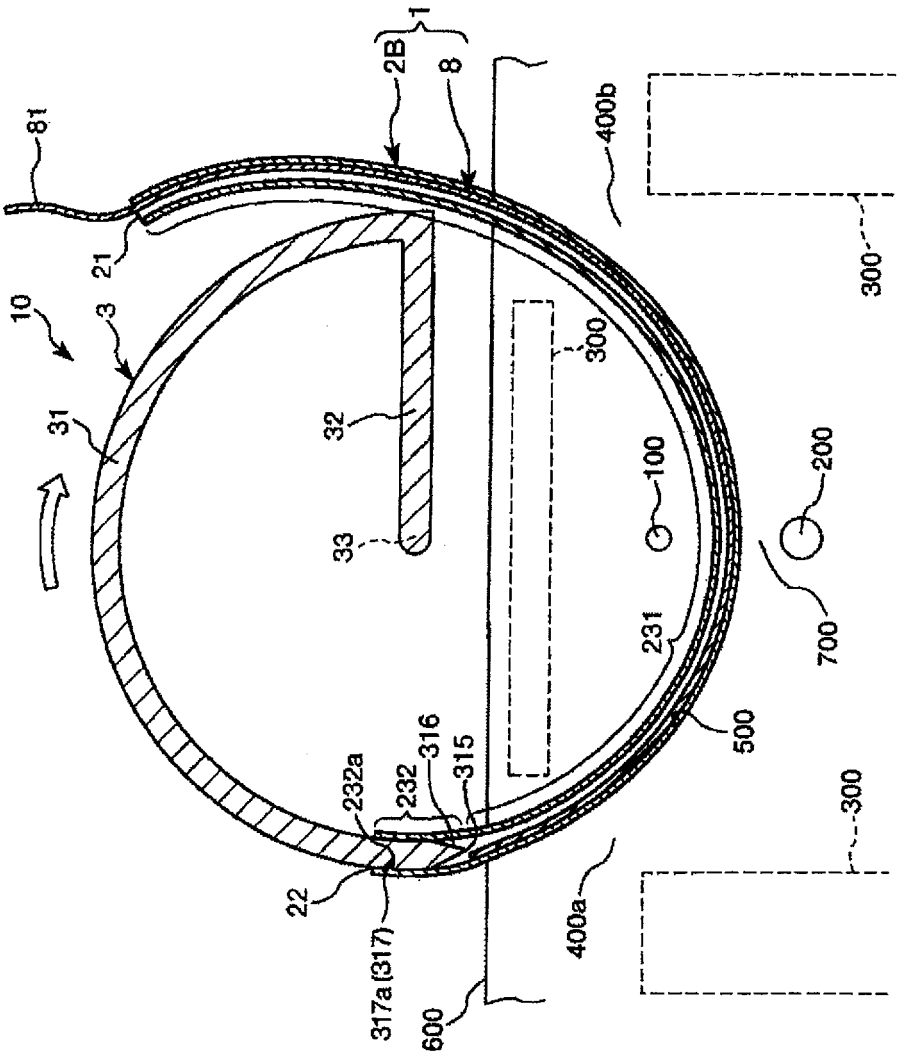

1
2B
8
81
21
10
3
31
32
33
400b
300
100
200
700
231
500
316
315
232a
232
22
317a (317)
600
400a
300

FIG. 15

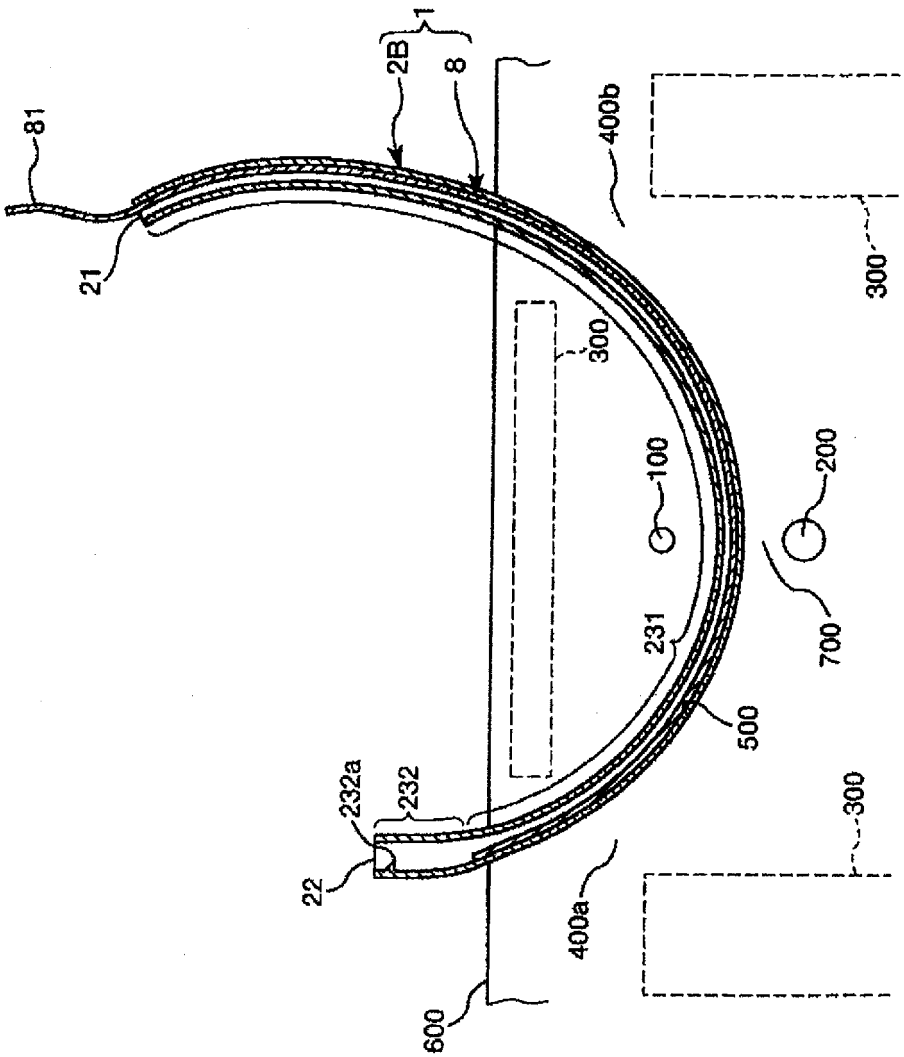

81
21
2B
1
8
400b
300
300
100
200
700
231
500
232a
232
22
300
400a
600

FIG.16

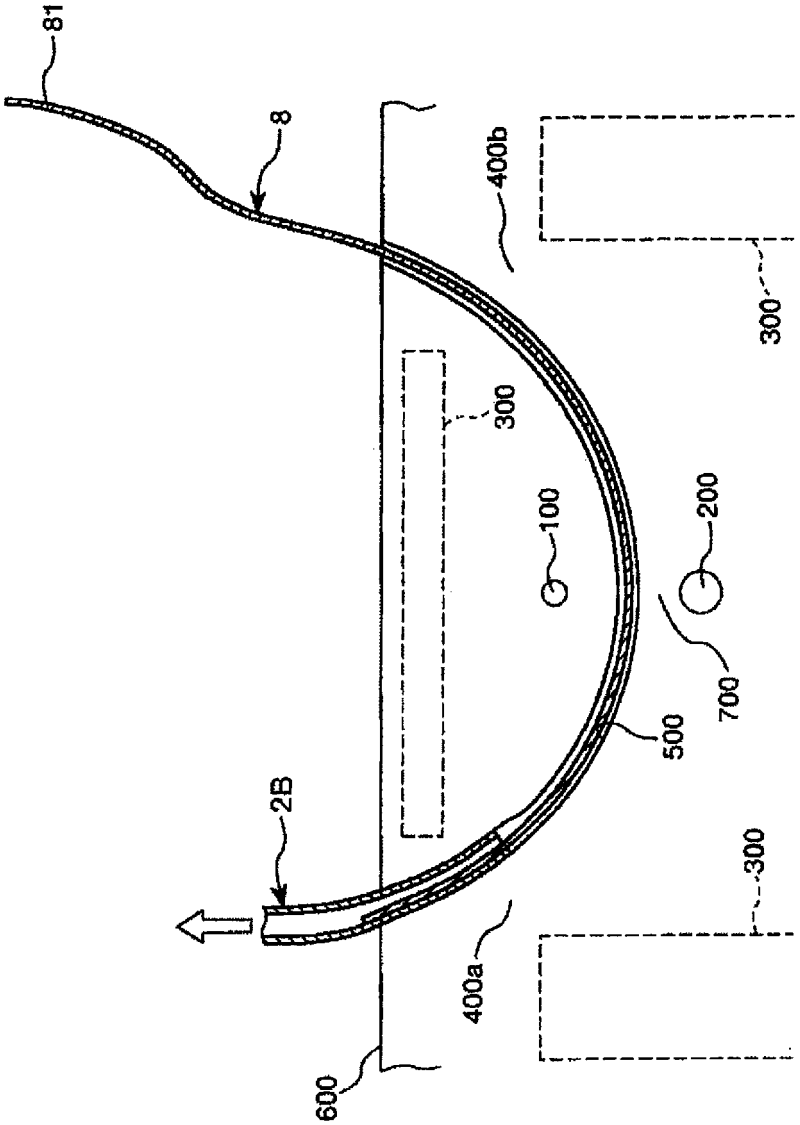


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2012/071593

A. CLASSIFICATION OF SUBJECT MATTER
A61F2/08(2006.01)i, *A61B17/00*(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F2/08, A61B17/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1922-1996	Jitsuyo Shinan Toroku Koho	1996-2012
Kokai Jitsuyo Shinan Koho	1971-2012	Toroku Jitsuyo Shinan Koho	1994-2012

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	JP 2006-517115 A (Boston Scientific Ltd.), 20 July 2006 (20.07.2006), paragraphs [0077], [0284] to [0295]; all drawings & US 2004/0087970 A1 & US 2005/0131391 A1 & US 2005/0131392 A1 & US 2005/0131393 A1 & US 2008/0139877 A1 & WO 2004/016196 A2 & CA 2495666 A1 & CA 2705609 A1	15-17 1-14
A	JP 2001-511684 A (Boston Scientific Ltd.), 14 August 2001 (14.08.2001), entire text; all drawings & US 6423080 B1 & EP 1402822 A2 & WO 1998/035616 A1 & DE 69821127 T2	1-17

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search 05 November, 2012 (05.11.12)	Date of mailing of the international search report 13 November, 2012 (13.11.12)
Name and mailing address of the ISA/ Japanese Patent Office Facsimile No.	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2012/071593

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2005-514967 A (Ethicon, Inc.), 26 May 2005 (26.05.2005), entire text; all drawings & US 2002/0077526 A1 & WO 2002/098322 A1 & CA 2449474 A1 & CN 1633263 A	1-17

Form PCT/ISA/210 (continuation of second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2012/071593

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

The inventions of claims 1 to 14 are inventions relating to a medical tube, and the inventions of claims 15 to 17 are inventions relating to an insertion needle.

Both the inventions cannot be considered to have a same or corresponding special technical feature in the light of the contents disclosed in (JP 2006-517115 A (Boston Scientific Ltd.), 20 July 2006 (20.07.2006), paragraphs [0077], [0284] to [0295]; all drawings).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2009)

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- JP 2010099499 A **[0005]**